with COPD, a total of 33.3% patients showed moderate to severe depressive symptoms and nearly 50% of cases had a marked impairment in HRQol. Educational and occupational status, body mass index, FEV1, respiratory symptoms, physical impairment and dyspnoea were associated with the diagnosis of depression in patients with COPD, whereas, body- mass-index, forced expiratory volume in 1 second (FEV1), dyspnea grade, and depression were associated with poor HRQL in patients with COPD. **CONCLUSIONS:** More than one third of patients with COPD had either depression or poor HQol in India. The study suggest need for regular screening for depression and HRQol in patients with COPD especially among obsese and patients with comprosised or severe respiratory functions.

PRM92

MEASURING THE SYMPTOMS AND IMPACTS OF ENDOMETRIOSIS: PSYCHOMETRIC VALIDATION OF THE ENDOMETRIOSIS SYMPTOM DIARY AND ENDOMETRIOSIS IMPACT SCALE

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OBJECTIVES: As a disease characterized by pain, Patient-Reported Outcomes (PROs) are important for determining disease severity and evaluating the efficacy of endometriosis treatments. In the absence of existing PROs that comply with the FDA PRO Guidance, two new PROs have been developed: The Endometriosis Symptom Diary (ESD) and Endometriosis Impact Scale (EIS). The content validity of these instruments has been demonstrated by extensive qualitative and quantitative research with women with endometriosis. The first investigations of the reliability and validity of scores derived from the ESD and EIS are presented herein. **METHODS:** Women with surgically-confirmed endometriosis (n=268) in the US and Germany participated in a 12-week non-interventional study. A range of PRO measures were completed by participants throughout the study using an electronic handheld device, including: ESD, EIS, Biberoglu & Behrman Scale, Endometriosis Health Profile-30, Patient Global Impression of Severity and Change measures and single-item pain numerical-rating and visual analogue scales. Pre-specified analyses were conducted to evaluate the test-retest reliability, convergent validity, known-groups validity and responsiveness of scores derived from the ESD and EIS. **RESULTS:** Intraclass correlation coefficients among participants classified as 'stable' support the test-retest reliability of ESD/EIS scores. Correlations between scores for the ESD/EIS and concurrent measures were consistent with a priori hypotheses, demonstrating convergent validity. Furthermore, Analysis of Covariance models revealed statistically significant ($p<0.05$) differences in ESD/EIS scores among participants of varying levels of symptom severity (as determined by scores on concurrent measures). Finally, observed ESD/EIS score changes in participants whose clinical status had improved (according to scores on concurrent measures) were significantly greater than those who had not improved/changed, providing evidence of responsiveness. **CONCLUSIONS:** Findings support the reliability and validity of scores derived from the ESD and EIS. Future research will seek to explore definitions of meaningful change in ESD/EIS scores using data from clinical studies.

PRM93

WHAT TYPE OF RESPONSE SCALE IS THE MOST RESPONSIVE? A COMPREHENSIVE REVIEW OF RESPONSE SCALE OPTIONS FOR PATIENT-REPORTED OUTCOME MEASURES

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OBJECTIVES: Selection of response scales for patient-reported outcome (PRO) measures is often driven by therapeutic area convention or preferences of measure developers. To help guide response scale selection, an objective of this project was to identify empirical evidence supporting the responsiveness of common response scale types. **METHODS:** A comprehensive literature review was conducted for studies published from January 2004 through October 2014 that provided direct comparisons of responsiveness of different response scale types. Additional searches were conducted for abstracts and presentations on this topic from relevant scientific conferences. **RESULTS:** The most common types of response scales evaluated were the 100mm visual analog scale (VAS), the 11-point numeric rating scale (NRS), and the verbal rating scale (VRS) (with varying number of levels). Three studies directly compared responsiveness of all three types. Of these, one found no difference in responsiveness of the three types, one found superior responsiveness for the NRS compared to the VAS, and one found the VAS to be most responsive for one domain while the NRS was most responsive for another. Three studies compared VAS to VRS, with one finding no difference and one study each finding greater responsiveness for the VAS and a 7-point VRS, respectively. Four studies compared NRS vs. VRS, with three demonstrating no difference and one demonstrating superior responsiveness for the NRS compared to a 6-point VRS. **CONCLUSIONS:** There are a number of considerations in response scale selection, including target population, study design, concept of interest, recall period, data collection mode, and scale responsiveness. Several reviewed studies demonstrated equivalent responsiveness for the most common response scale types; however, evidence suggests the 11-point NRS may be slightly more responsive than the other response scales in some settings. Limitations of this review include its 10-year timeframe and the paucity of empirical studies comparing common response scales.

PRM94

PSYCHOMETRIC VALIDATION OF THE FATIGUE SYMPTOMS AND IMPACTS QUESTIONNAIREâ€"RELAPSING MULTIPLE SCLEROSIS (FSIQ-RMSâ„¢)

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OBJECTIVES: Fatigue is an important symptom for multiple sclerosis (MS) patients. Qualitative research supported initial content validity of the FSIQ-RMS™,1 the first patient-reported outcome (PRO) measure of fatigue in relapsing (R)MS developed according to the 2009 FDA PRO guidance. To confirm appropriateness, validity, and reliability of the FSIQ-RMS, further psychometric analyses were required. **METHODS:** The FSIQ-RMS™ with 9 Symptom items (daily recall period, 1 subdomain) and 14 Impact items (weekly recall period, 3 subdomains) was administered over 3 months (three 7-day intervals) in a multicenter, non-interventional, US-based, IRB-approved study to adult patients with different RMS subtypes (relapsing remitting, secondary progressive, progressive relapsing) and a subset of matched healthy controls (week 1 only). Data analyses included: item response and dimensionality; content and construct validity; internal consistency and test-retest reliability; as well as attribution of fatigue to RMS. Evaluations were supported by those from a cross-sectional, multicenter study, in which RMS patients completed the FSIQ-RMS™ Symptoms domain. **RESULTS:** The psychometric validation study included 164 RMS patients (mean age 45 [range 19–65] years; 76% female) and 74 controls (40 [18–65] years; 73% female). Two redundant Symptom items were deleted, leaving 7; Impact items were unchanged. A 0–100 scoring algorithm was developed for the FSIQ-RMS™ (sub)domains. Internal consistency (Cronbach's alpha 0.87–0.97) and test-retest reliability (intraclass correlation coefficient [ICC] 0.92–0.95) of all (sub)domains exceeded pre-specified thresholds (alpha>0.70; ICC≥0.70). The Symptoms domain discriminated along the symptom-severity continuum of RMS patients and between patients and healthy controls. Patients were able to attribute fatigue-related symptoms to RMS (14-point difference vs. controls; $P<0.0001$). Findings were supported by those from the cross-sectional study (N=154). **CONCLUSIONS:** Content and measurement validity of the revised final FSIQ-RMS™ were confirmed. Responsiveness of the PRO will be evaluated in a Phase III trial. 1Value Health 2014;17(3):A195-6.

PRM95

FEASIBILITY OF USING THE SF-36 HEALTH SURVEY TO SCREEN FOR RISK OF MAJOR DEPRESSIVE DISORDER

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OBJECTIVES: To assess the feasibility of the SF-36v2 Mental Health (MH) domain and Mental Component Summary (MCS) scores in the classification of risk for major depressive disorder (MDD), and determine the cutoff scores in a US sample and chronic pain subpopulations. **METHODS:** Data were analyzed from the 2013 US National Health and Wellness Survey (adults ≥18 years old; N=75,000). Respondents were also classified into subpopulations based on self-report: chronic pain (n=6,679) and chronic pain receiving medication for depression (i.e. with depression) (n=5,814). The primary definition for classifying respondents at risk of MDD was a score > 10 on the Patient Health Questionnaire (PHQ-9). Logistic regression modeling was used to predict at risk for MDD, or not, and receiver operating characteristic curves were produced. **RESULTS:** The total sample had MH scores of 48.8 and MCS scores of 48.9, similar to the normative mean for the US adult population. The percent of respondents with a PHQ-9 > 10 were 15.0%, 29.1% and 25.9% for the total sample, chronic pain alone, and chronic pain with depression, respectively. Cutoff scores (PHQ-9>10) in the total sample for the MH domain and MCS were 43.0 and 46.0, respectively. Specificities of recommended cutoff scores for the MH domain and MCS were 77.8% and 76.1%; sensitivities were 84.9% and 88.1%. Among the subpopulation with chronic pain alone, cutoff scores for the MH domain and MCS were 40.4 and 43.1, respectively. Corresponding specificities for the MH domain and MCS were 77.9% and 73.9%; sensitivities were 78.3% and 83.4%. Trends were similar among the chronic pain with depression subpopulation. **CONCLUSIONS:** The SF36v2 was found to have sufficient specificity and sensitivity to categorize participants at risk for MDD. It is feasible to use the SF-36v2, a widely used measure to assess health status, to better characterize the mental health of populations.

PRM96

EXAMINING THE RELATIONSHIP BETWEEN HEALTH-RELATED QUALITY OF LIFE AND INCREASING NUMBERS OF DISEASES

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OBJECTIVES: Little is known about estimating utilities for comorbid (or 'joint') health states. Several joint health state prediction models have been suggested (for example, additive, multiplicative, best-of-pair, worst-of-pair, etc.) but no general consensus has been reached. Without preconceptions about the preferred functional form, this study explores the relationship between health-related quality of life (HRQoL) and increasing numbers of diagnoses. **METHODS:** We analyzed a large dataset containing respondents' ICD-9 diagnoses and preference-based HRQoL (EQ-5D and SF-6D). Data were stratified by the number of diagnoses and mean HRQoL values were estimated. Several adjustments, accounting for the respondents' age, sex and the severity of the diagnoses were carried out. Our analysis fitted additive and multiplicative models to the data, and assessed model fit using multiple standard model selection methods. **RESULTS:** A total of 39817 respondents were included in the analyses. Average HRQoL values were represented well by both linear and multiplicative models. Although results across all analyses were similar, adjusting for severity of diagnoses, age and sex strengthened the linear model's performance measures relative to the multiplicative model. Adjusted values were above 0.99 for all analyses (i.e. all adjusted analyses, for both HRQoL instruments), indicating a robust result. **CONCLUSIONS:** Additive and multiplicative models perform equally well within our analyses. Presupposing that a linear model is simpler than an additive one, we conclude that the additive model should be preferred unless compelling evidence is produced to show that the models diverge.

PRM97

ELICITING PATIENT TREATMENT PREFERENCES: DEVELOPMENT OF A METHODOLOGICAL FRAMEWORK FOR ATTRIBUTE IDENTIFICATION AND VALIDATION FOR DISCRETE CHOICE EXPERIMENTS

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OBJECTIVES: Measurement of the risk-benefit tradeoffs in healthcare decision-making relies on capturing preferences for treatment attributes that are most important to individuals. The goal of this study is to develop and validate a methodological framework for identifying, validating, and prioritizing attributes for inclusion in discrete choice experiments (DCE). **METHODS:** The study enrolled 48 caregivers of a child aged 26 or younger diagnosed with an intellectual disability and mental health disorder. Data were collected through IDIs (n=6) and six focus groups (n=42). Following qualitative methods for grounded theory and content analysis, data were analyzed in four distinct steps. First, in-depth interviews (IDIs) were analyzed to identify concepts reflecting distinct situations influencing treatment decisions. Second, the concepts were validated by researcher-caregiver agreement in defining the concept. Third, caregivers prioritized the concepts by selecting those that were most influential in making treatment decisions for their child. Fourth, a final list of attributes was chosen based on the subset of attributes that had high researcher-caregiver agreement and that were a high priority. Triangulation, member checking, and participants' and stakeholder partners' feedback was used throughout the process. **RESULTS:** Sixteen concepts were identified from the IDIs. Researcher-caregiver agreement in concept definition ranged between 21-79%. The concepts rated as high priorities in decision-making were managing the child's behavior, advocating for the child's needs, and communicating with providers. The financial impact and getting a label were low priorities in treatment decisions. Seven concepts rated as low priorities and with low definition agreement were discarded. This resulted in a final list of nine attributes. **CONCLUSIONS:** Systematic methods for attribute identification, as well as stakeholder involvement, will inform the development of DCE instruments that closely reflect risk-benefit tradeoffs in healthcare decisions. Methodological standards for attribute identification would enhance the application and interpretation of DCE in preference elicitation.

PRM98

PHARMACISTS-LED INTERVENTIONS TO IMPROVE HEALTH-RELATED QUALITY OF LIFE OF PULMONARY TUBERCULOSIS PATIENTS IN PAKISTAN: AN INSIGHT FROM A RANDOMIZED CONTROLLED NON-CLINICAL TRIAL

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OBJECTIVES: To evaluate the importance of a health-educational interventional program to improve Health-Related Quality of Life (HRQoL) among Pulmonary Tuberculosis (PTB) patients in Pakistan, under the supervision of registered hospital pharmacists. **METHODS:** A health-educational intervention to improve HRQoL was offered to the PTB patients through registered hospital pharmacists. In this non-clinical randomized controlled trial, PTB patients were briefed regarding treatment and management of PTB and their HRQoL was measured by WHOQOL-BREF. Both descriptive and inferential statistics were used to determine patients' demographic characteristics and inter-group comparisons respectively. Data was analyzed by SPSS 21.0. **RESULTS:** Two hundred and eighty PTB patients were randomly assigned for the study i.e. one hundred and forty patients in each group. No significant differences were observed in either group for mean age, gender, education level, occupation and income whereas a significant increase ($p<0.001$) in the WHOQOL-BREF score was observed in the interventional group. **CONCLUSIONS:** HRQoL was significantly improved in the interventional group after the pharmacist-led interventional program which advocates the vital role of pharmacists in patients' education and a better health care system of Pakistan.

PRM99

DEVELOPING SF-6D-V2: EXAMINING THE DIMENSIONALITY OF THE SF-36 USING LARGE MULTINATIONAL DATASETS

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OBJECTIVES: The SF-36 is a measure of health related quality of life that is widely used internationally. SF-36 produces scores for eight dimensions (physical functioning (PF); role physical (RP); bodily pain (BP); general health (GH); vitality (VT); social functioning (SF); role emotional (RE); mental health (MH). However there is debate about whether these dimensions are applicable cross culturally, and also the relationship between the MH and VT dimensions. The aim was to assess the dimensionality using multinational datasets as part of the development of SF-6D-V2. **METHODS:** Exploratory and confirmatory factor analysis was used to examine SF-36 dimensionality, and was applied to patient and general population datasets from the UK, Australia, Canada, USA and Japan (n = 55,923). Analysis was carried out separately for each country, and on the combined data. The general health items were not included as the focus was the specific health areas measured by SF-36. **RESULTS:** Exploratory factor analysis on the data from the English speaking countries suggests that the PF, RF, BP, SF and RE dimensions are generally consistent but there are inconsistencies regarding the MH and VT, where the items split into factors based on whether the item is positively or negatively worded. The data from Japan suggests that the role dimensions do not split into physical and emotional constructs. Confirmatory analysis suggests that both the original seven factor model, and a model splitting MH and VT based on the direction of the items, fit the data acceptably. **CONCLUSIONS:** There is evidence for cross cultural differences in the role functioning dimensions of the SF-36, most likely due to differences in the perception of emotional health. The inconsistency of the MH and VT dimensions may be due to the combination of positive and negative items, order effects, or content overlap.

PRM100

DEVELOPMENT AND VALIDATION OF THE PROMIS NETWORK TO EVALUATE PATIENT-REPORTED HEALTH STATUS ASSOCIATED WITH CLOSTRIDIUM DIFFICILE INFECTION

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OBJECTIVES: The Patient-Reported Outcome Measurement Information System (PROMIS), funded by the National Institute of Health (NIH) is a large database of precise measures of patient-reported health status for physical, mental, and social well-being. Use of the PROMIS tools to evaluate humanistic outcomes in hospitalized patients with Clostridium difficile infection (CDI) has not been studied. The objective of this study was to identify and validate the use of specific PROMIS network questions to evaluate patient-reported health status associated with CDI. **METHODS:** This was a prospective, observational, two-center, mixed-methods study. Hospitalized adult patients with CDI were interviewed within seven days of a positive toxin test for C. difficile and again within one week of hospital discharge (N = 40). Patients were asked open-ended questions regarding their top three concerns related to CDI. Results were analyzed using ATLAS.ti 7 and classified by PROMIS domains. Based on response trends, applicable standardized questions from the PROMIS network were identified. An additional 15 patients with CDI were interviewed using the PROMIS questions to validate relevant questions. **RESULTS:** Patient reported humanistic outcomes within seven days of CDI diagnosis were primarily associated with mental concerns (75%) related to anxiety and worry about future complications. Physical concerns (8%) were related to ongoing diarrhea, bowel incontinence and other abdominal complaints. Social concerns (3%) included interference with daily living and finances. Patient reported outcome responses did not change significantly during the follow-up interview. Using these responses from direct interviews of CDI patients, 18 PROMIS network questions were identified and demonstrated evidence of reliability. **CONCLUSIONS:** Using the NIH PROMIS network, we identified 18 patient-reported health status questions that can be used to evaluate humanistic outcomes in patients with CDI. Future studies should use these questions to assess changes in health status of CDI patients over time.

PRM101

VALIDATION AND VALUATION OF THE PREFERENCE-BASED HEALTHINDEX USING EQ-5D-5L IN THE HONG KONG POPULATION

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OBJECTIVES: The EQ-5D is a preference-based measure of health for economic evaluation. This study is to develop a Hong Kong (HK) Chinese version of EQ-5D-5L and value set in estimating the health utility in local population. **METHODS:** This study consists of three parts including (I) Translation and Cultural Adaptation of the HK Chinese version of EQ-5D-5L by forward/backward translation and lay panel assessment; (II) Valuation Study of EQ-5D-5L HK by a cross-sectional population-based survey; and (III) Creation of norms values in HK by secondary analysis of data from part II study. 20 respondents and 1,000 respondents aged ≥18years old will be recruited for part I and II study respectively. Subjects are quota sampled by geographic area and demographic characteristics (gender, age and education level) based on the comparison of HK population in the HK Census 2011. **RESULTS:** In part I: Forward/backward translation of the English version of EQ-5D-5L are performed based on the translation protocol of the EuroQol group, cognitive interview with 20 laymen which are conducted for cultural adaption of the HK Chinese version of EQ-5D-5L. The HK Chinese version of EQ-5D-5L (EQ-5D-5L HK) is validated. In part II: A total of 475 out of 1000 subjects were recruited for face-to-face interviews with computer-assisted using EQ-5D-5L HK. The sample (38.9% in 18-44 yrs; 36.6% in 45-64 yrs; 24.4% in 65 yrs and above) was predominantly female and with a secondary education level. **CONCLUSIONS:** A preference-based values using EQ-5D-5L HK are to be collected from the general population in HK. This value set data will then be used to derive an algorithm model to estimate the preference-based health index in the Hong Kong population. The norms of health-related quality of life in Hong Kong population using EQ-5D-5L will be presented by different demographic groups including age, gender and education level.

PRM102

USABILITY TESTING OF THE WEB-BASED VERSIONS OF THE STANDARDISED ASTHMA QUALITY OF LIFE QUESTIONNAIRE FOR 12 YEARS AND OLDER (AQLQ(S)+12) AND THE ASTHMA CONTROL QUESTIONNAIRE (ACQ-6)

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OBJECTIVES: The main objective of this study was to assess the usability of the newly developed web-based UK versions of the Standardised Asthma Quality of Life Questionnaire for individuals12 years and older (AQLQ(S)+12) and the Asthma Control Questionnaire (ACQ-6). **METHODS:** Individual interviews were conducted with eight patients with asthma. During the session, each patient was requested